PATENT COOPERATION TREATY

PCT

10/518860

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TETR 763803WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/50231	International filing date *(day/month/year)* 17.06.2003	Priority date *(day/month/year)* 18.06.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/06		
Applicant F.R.I.D. R&D BENELUX SPRL et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.01.2004	29.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Neumann, E Telephone No. +31 70 340-3028

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/50231

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-4, 6, 8, 9	as originally filed
5, 5a, 7	received on 11.06.2004 with letter of 08.06.2004

Claims, Numbers

1, 2	received on 11.06.2004 with letter of 08.06.2004

Drawings, Figures

1-3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1, 2
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 2
Industrial applicability (IA)	Yes:	Claims	1, 2
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I
Basis of the report

1. The amendments made in claim 1 filed with the International Bureau under Article 19(1) introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. The amendments concerned are the following:

1.1 "A multilayer luminal self-expanding stent" could only have been replaced by "A multilayer **braided** luminal self-expanding stent" (see original claim 1 and description page 5, lines 26 - 27).

1.2 "A outer peripheral stent structure (10)" could only have been replaced by "An outer **braided** peripheral stent structure (10)" (see original claim 1 and description page 5, line 28; "an" instead of "a" is a writing mistake).

1.3 In original claim 1 and description page 5, lines 26 - 31, only the "filaments" make part of the common braided structure and not as it is amended in claim 1 that "filaments", "outer **braided** peripheral stent structure (10)" and the "central hollow braided core" make part of the common braided structure.

The remainder of this communication is based on the assumption that claim 1 is to be interpreted as above.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:

D1: WO 01/01887 A (SCIMED LIFE SYSTEMS INC) 11 January 2001 (2001-01-11)

2. 2.1 The present claim 1 does not meet the requirements of Article 33 (2) PCT, because its subject-matter is not new.

2.2 Document D1 discloses (see page 6, lines 15 - 18; page 9, line 29 - page 10, line 5;

figure 4):

A multilayer **braided** luminal self-expanding stent (22) for an anatomical conduit, expandable from a reduced diameter to a nominal diameter, comprising **an** outer **braided** peripheral stent structure (24) *wherein*
said outer **braided** peripheral stent structure (24) is permanently linked to a central hollow braided core (2) acting as an inner braided hemodynamic flow deflector by at least a pair of filaments (12);
said at least a pair of filaments (12) make part of a common braided structure, a gap of between 10 to 90% of the nominal diameter of the outer **braided peripheral** stent **structure** (24) extending between the inner and outer parts of the common braided structure.

Although document D1 mentions that the stent in the form of filaments may be adhered to the inner and/or outer layer it implies as well that the stent may also be NOT adhered to its neighbouring layers (see page 11, lines 20 - 22). In that case, and although it is not explicitly mentioned, there is a gap between the inner (2) and outer (24) parts of the stent in D1 (see figure 4) which can be seen as 10% of the nominal diameter of the outer **braided** peripheral stent structure (24).

3. Claim 2 is not clear (Article 6 PCT) for the following reasons:
if the "outer braided peripheral stent structure" is comprised of first and second layers which are connected by filled "wires" (see also paragraph 5.1) in order to connect them to the "deflector" which again comprises these two layers it only means that basically the "deflector" contains the features of the "outer braided peripheral stent structure". These features are already known in claim 1 and no new aspect is added in claim 2. It cannot be interpreted that the "outer braided peripheral stent structure" and the "deflector" each comprise a double layer structure.

4. Dependent claim 2 does not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty, see for example:

4.1 D1, see page 6, lines 15 - 18; page 9, line 29 - page 10, line 5; figure 4 for claim 2.

increased along the cell wall, consequently improving the shear stress at wall level.

During the 12th conference of the European Society of Biomechanics (Dublin 2000) Nikos Stergiopolos demonstrated that avoiding intimal hyperplasia proliferation mainly in the case of low flow could be done by placing a streamlined cylindrical body in the centre of blood stream. The body deflects the central core of flow towards the wall, increasing the wall shear stress.

However, this brilliant theory could hardly be reduced to practice. The placing of a cylinder in the centre of the stream line of a diseased artery is not easy by itself, and it needs to be coupled with the prior placing of a standard stent, both to hold the atherosclerosis plaques and to anchor the cylinder. The inner cylinder further needs to be stable and firmly held in place.

The Applicant has developed a stent made out of a plurality of interlaced braided layers of metal filaments.

Prior experience in this field allowed him to develop a new type of stent which is braided in such a way that the making of a peripheral stent, a central deflecting cylinder and a linking between these two elements is achieved in a single shot.

The subject of the invention is a multilayer braided luminal self-expanding stent for an anatomical conduit comprising a outer braided peripheral stent which is permanently linked to an inner braided hemodynamic flow deflector by at least two filaments that make part of the common braided structure, the gap between the two commonly braided structures is broadly between 10 to 90% of the nominal diameter of the outer stent.

Brief description of the figures

Other particulars and advantages of the invention will become apparent from the description hereinafter of some particular embodiments of the invention, reference being made to the appended drawings in which:

Fig. 1 is a sketch of the aspect of the blood flow, with and without the inner core of a stent according to the invention.

Fig. 2 is a sketch of a sectional view along the axis of the stent.

Fig. 3 is a sketch of a sectional view normal to the axis of the stent

Detailed description of the figures

Fig. 1 shows a diagrammatical view of the velocity profile of a flow of blood, with (right side of the Fig 1) or without (left side of the Fig 1) the hemodynamic deflecting core 2 of the stent of the invention 4.

In the absence of core 2, the velocity cube 6a is classical: the velocity decreases progressively from a maximum to zero at the very contact of the wall 8, allowing the anarchic growth of wall cells that in time will impede the even passage of blood.

Turning now to the left side of the figure, one can see that the blood, deflected from the centre of the vessel by the hemodynamic core 2, induces a steeper flow profile 6b near the wall 8. The shear stress thus improved drags along the molecules that would induce a reaction of the wall cells.

Fig. 2 and 3 display the general structure of the stent 4, that exhibits a central hollow braided hemodynamic core 2 and a "classical" peripheral stent

CLAIMS

1.- A multilayer braided luminal self-expanding stent (4) for an anatomical conduit (8), expendable from a reduced diameter to a nominal diameter, comprising a outer braided peripheral stent (10) which is permanently linked to an inner braided hemodynamic flow deflector (2) by at least a pair of filaments (12) that make part of a common braided structure, a gap of between 10 to 90% of the nominal diameter of the outer stent (10) extending between the inner and outer parts of the commonly braided structure.

2.- A multilayer stent according to claim 1 characterised in that the outer structure (10) comprises a first and a second layer which are connected by at least a pair of filled wires (12) in order to connect the first two layers to the deflector, the latter comprising last two layers.